



PATENT

Attorney Docket No.: 18184-0003US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Patent application of
Herbert W. Harris, *et al.*

Serial No. 10/728,179

Filing Date: December 3, 2003

For: PHARMACEUTICAL COMPOSITION OF 1-
(3-HYDROXY-4-METHOXYPHENYL)-4-
METHYL-5-ETHYL-7,8-DIMETHOXY-5H-
2,3-BENZODIAZEPINE AND USES
THEREOF

Group Art Unit:
1617

Examiner:
Layla Soroush

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

04/18/2008 HLE333 00000016 10728179
01 FC:1806 180.00 OP

Sir:

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, submitted herewith are copies of the references listed in the accompanying form PTO-1449, except for any U.S. patents and published U.S. patent applications which may be listed.

The Examiner is respectfully requested to review the items listed on the PTO Form 1449 and make them of record in the instant application as required by M.P.E.P. §609. It is requested that the Examiner initial the enclosed duplicate substitute Form 1449, and return one copy to the undersigned.

CERTIFICATE OF MAILING
UNDER 37 C.F.R. 1.8(a)

I hereby certify that this paper, along with any paper referred to as being attached or enclosed, is being deposited with the United States Postal Service on the date indicated below, with sufficient postage, as first class mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

BY

Jennifer R. Hanna

DATE:

4/15/08

This Information Disclosure Statement should not be construed as a representation that the cited references are material or prior art, or that more relevant references do not exist.

This Statement is being submitted after receipt of an office action on the merits. The \$180 fee under 37 C.F.R. 1.17(p) is submitted herewith.

Concise Explanation of Relevance of Non-Language Information

A concise explanation of the relevance of DE2940483A1 (hereinafter DE'483A1") is as follows. The aforesaid document was cited in the Supplementary European Search Report of the European counterpart of the present application, European application 03815301. The search report stated the relevance of DE'483A1 as follows:

- * page 17 - page 21*
- * page 33 - *
- * page 66; example 39 *

The concise explanation of the relevance of document DE2940483C2 (hereinafter DE'483C2") is as follows. DE'483C2 is believed to be the examined, republished counterpart of DE2940483A1.

Remarks

The claims presently pending and subject to examination are directed to pharmaceutical compositions comprising a pharmaceutically acceptable carrier and 1-(3-hydroxy-4-methoxyphenyl)-4-methyl-5-ethyl-7,8-dimethoxy-5H-2,3-benzodiazepine, or a pharmaceutically acceptable salt thereof. The subject compound is not disclosed in the typewritten text of DE'483A1. However, Example 39 ("Beispiel 39") at page 66¹ contains a handwritten interlineation changing the typewritten compound name "1-(3'-Methoxy-4'-hydroxyphenyl)-4-methyl-5-äthyl-7,8-dimethoxy-5H-2,3-benzodiazepin" to "1-(3'-Hydroxy-4'-methoxyphenyl)-4-methyl-5-äthyl-7,8-dimethoxy-5H-2,3-benzodiazepin" (emphasis added). The typewritten text is

¹ Reference to page numbers of DE'483A1 are to the handwritten page numbers appearing in that document.

translated into English as 1-(3'-methoxy-4'-hydroxyphenyl)-4-methyl-5-ethyl-7,8-dimethoxy-5H-2,3-benzodiazepine. The handwritten interlineation purports to change the compound name to 1-(3'-hydroxy-4'-methoxyphenyl)-4-methyl-5-ethyl-7,8-dimethoxy-5H-2,3-benzodiazepine.

It is respectfully submitted that the handwritten modification of DE'483A1, Example 39, should not be regarded as a disclosure of the compound 1-(3'-hydroxy-4'-methoxyphenyl)-4-methyl-5-ethyl-7,8-dimethoxy-5H-2,3-benzodiazepine, since the handwritten portion conflicts with the printed name of the same Example 39 ("Beispiel 39") compound as given at the second entry at Table 2, page 44: "1-(3'-Methoxy-4'-hydroxyphenyl)-4-methyl-5-äthyl-7,8-dimethoxy-5H-2,3-benzodiazepin". The name of the Example 39 compound was not changed in Table 2 from "1-(3'-Methoxy-4'-hydroxyphenyl)..." to "1-(3'-*Hydroxy*-4'-*methoxy*phenyl)...", as was done at page 66. One of ordinary skill in the art would therefore not be inclined to accept the accuracy of the handwritten modification of the Example 39 compound name at page 66, in view of the unchanged occurrence of the compound name in Table 2 at page 44.

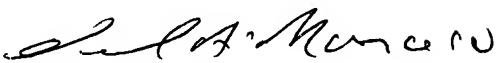
The text of DE'483C2, the examined republished counterpart of DE'483A1, provides further evidence that one skilled in the art would understand Example 39 of DE'483A1 to represent the compound 1-(3'-methoxy-4'-hydroxyphenyl)-4-methyl-5-ethyl-7,8-dimethoxy-5H-2,3-benzodiazepine, and not 1-(3'-*hydroxy*-4'-*methoxy*phenyl)-4-methyl-5-ethyl-7,8-dimethoxy-5H-2,3-benzodiazepine. The C2 document discloses only the 3'-methoxy-4'-hydroxyphenyl compound, and not 3'-*hydroxy*-4'-*methoxy*phenyl compound. See DE'483C2, Table 2, p. 7, the 3rd from the last entry. The purported 3'-*hydroxy*-4'-*methoxy*phenyl compound is not found anywhere in the text of DE'483C2.

As yet further evidence that the compound in question in DE'483A1 would be understood as 1-(3'-methoxy-4'-hydroxyphenyl)-4-methyl-5-ethyl-7,8-dimethoxy-5H-2,3-benzodiazepine, and not 1-(3'-*hydroxy*-4'-*methoxy*phenyl)-4-methyl-5-ethyl-7,8-dimethoxy-5H-2,3-benzodiazepine, attention is directed to US Pat. 4,322,346 (of record), which claims the same priority as DE'483A1, that is, Hungarian Patent Application GO 1426, filed Oct. 19, 1978. The US '346 patent discloses only 1-(3'-methoxy-4'-hydroxyphenyl)-4-methyl-5-ethyl-7,8-dimethoxy-5H-2,3-benzodiazepine. There is no disclosure of 1-(3'-*hydroxy*-4'-*methoxy*phenyl)-4-methyl-5-ethyl-7,8-dimethoxy-5H-2,3-benzodiazepine anywhere in the disclosure of US'346.

It is respectfully submitted that one skilled in the art would disregard the purported handwritten modification of the Example 39 compound name in DE'483A1 to "1-(3'-*Hydroxy*-4'-*methoxy*phenyl)-4-methyl-5-äthyl-7,8-dimethody-5H-2,3-benzodiazepin", and would understand that compound to be 1-(3'-**methoxy**-4'-**hydroxy**phenyl)-4-methyl-5-ethyl-7,8-dimethody-5H-2,3-benzodiazepine.

Respectfully submitted,

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